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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,423	12/01/2000	Michael Houghton	1618.003	3252

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Chiron Corporation  
Intellectual Property - R440  
P.O. Box 8097  
Emeryville, CA 94662-8097

EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/728,423

**Applicant(s)**

HOUGHTON ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1- 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1- 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 22, 2004 has been entered.

Claims 1- 27 are under consideration.

### ***Rejections Withdrawn***

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 3, 5, 6, 8, 10, 12, and 14- 17 under 35 U.S.C. 102(a) as being anticipated by Forns *et al.* is withdrawn.

Applicant's arguments and amendments to the claims have been fully considered and found persuasive.

The rejection of claims 1- 5, 10, 14, 15, and 17- 25 under 35 U.S.C. 102(b) as being anticipated by Ishi *et al.* (Ishi) is withdrawn.

The claims as amended do not read on administration of virus accidentally.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 3, and 5- 26 under 35 U.S.C. 103(a) as being unpatentable over Forns *et al.* is maintained.

Applicant's arguments have been fully considered and found persuasive for reasons stated above.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds required for "not secreted" are.

Claims 1- 27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the structure that makes the peptides not be secreted. The claims contain a "wherein" clause that indicated that the proteins are not secreted. The "wherein" clause only indicates an inherent property of the recited structure. The recited structures are listed as full length or missing the p7 peptide (claim 1). Fournillier *et al.* teach that NOB responses were only obtained with truncated proteins, not full length (page 7498, column 1, first full

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paragraph). The recited structures include "full length" and thus read on wild type which are secreted except for the polynucleotide that lacks p7.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1- 6, 8, 10, 12, and 15- 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Fournillier *et al.*

The claims are drawn to eliciting an immune response using an HCV polynucleotide antigen. Claim 1 recites comprising E1E2 antigen but does not provide any other structural limitations for the wherein clause "not secreted" so it reads on any polynucleotide that encodes E1E2 and the antigen comprises an E1 polypeptide and an E2 polypeptide. The antigen comprising limitation requires only that the polypeptide contain some E1 and some E2 not the whole length of both.

Fournillier *et al.* teach a method of eliciting an immune response to HCV polynucleotides comprising E2 without p7 and a polynucleotide that comprises E1E2 (Figure 1a). These antigens induce an NOB antibody titer (Figure 4).

Thus, Fournillier *et al.* anticipates the claimed invention.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 5, 7, 10, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Yanagi *et al.*

The claims are drawn to eliciting an immune response using an HCV polynucleotide antigen. The recited fragments in claim 7 do not limit the administered polynucleotide to the recited sequence because claim 1 uses comprising language. Claim 1 recites comprising E1E2 antigen but does not provide any other structural limitations for the wherein clause not secreted so it reads on any polynucleotide that comprises E1E2 antigen.

Yanagi *et al.* teach eliciting an immune response to a polynucleotide comprising E1E2 antigen (page 8740, column 1, last paragraph).

Thus, Yanagi *et al.* anticipate the claimed invention.

### **Conclusion**

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill  
Patent Examiner  
August 9, 2004



JAMES HOUSEL 8/9/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600